European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Monthly Report of Application Procedures, Guidelines and Related Documents

The CVMP Monthly Report includes statistical data for the current year and the previous two ones on Scientific Advice, Initial Evaluations, Variations, Line Extensions, Renewals, MRLs Initial Evaluations and MRLs Extensions/Modifications and Arbitration and Referral procedures.
In addition, the report includes a summary table of the opinions issued by the CVMP in the current year and a list of adopted Guidelines and other public documents.

Applications for Medicinal Products for Veterinary Use and Maximum Residue Limits (MRLs)

Scientific Advice Requests

	95-05	2006	2007	2008	Total
Submitted	37	14	7	5	63

Initial Evaluation

	95-05	2006	2007	2008	Total
Full[1]	78	5	14	12	109
Abridged/Generics	3	3	1	3	10
Withdrawals	11	0	0	1	12
Positive Opinions	56	13	9	12	90
Negative Opinions	0	1	0	0	1

Marketing Authorisations

	95-05	2006	2007	2008	Total
Granted	56	10	9	11	86
Withdrawals	1	0	0	1	2
Not renewed	1	0	1	0	2

Extensions - Annex II Applications[2]

	95-05	2006	2007	2008	Total
Submitted	47	0	9	4	60
Withdrawals	1	0	0	0	1
Positive Opinions	30	2	1	7	40
Negative Opinions	0	0	0	0	0

Variations – Applications submitted

	95-05	2006	2007	2008	Total
Type IA	207	18	29	20	334
Type IB		13	24	23	
Type II	86	25	47	46	204
Transfers	6	1	2	2	11

[1] Initial applications submitted and validated: 119 applications in total (full + abridged), comprising 60 immunologicals and 59 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

[2] Extensions applications submitted and validated: 58 line extensions in total, comprising 11 immunologicals and 47 pharmaceuticals; one opinion can cover a number of extensions

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Renewals					
	95-05	**2006**	**2007**	**2008**	**Total**
Submitted	27	2	14	6	49
Positive Opinions	24	5	11	8	48
Negative Opinions	0	0	0	0	0

Establishment of MRLs for new substances					
	95-05	**2006**	**2007**	**2008**	**Total**
Submitted	60	3	2	1	66
Withdrawals	5	0	0	0	5
Positive Opinions[3]	44	5	3	2	54
Negative Opinions[4]	6	0	0	1	7

Arbitrations and Community Referrals					
	95-05	**2006**	**2007**	**2008**	**Total**
Referrals Submitted	11	10	6	11	38
Opinions Reached	-	4	10	5	19

Extensions / Modifications/Extrapolations of MRLs					
	95-05	**2006**	**2007**	**2008**	**Total**
Submitted	92	3	1	1	97
Withdrawals	4	0	0	0	4
Positive Opinions[3]	101	6	4	2	113
Negative Opinions[4]	5	1	0	0	6
Extrapolations	40	5	0	5	50

[3] Including opinions recommending definitive MRLs for substances with previously provisional maximum residue limits
[4] Including one opinion concluding that final MRL could not be established for a substance with provisional maximum residue limits previously established

CVMP Opinions in 2008 on Medicinal Products for Veterinary Use

Positive Opinions

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Reconcile ▪ fluoxetine (as fluoxetine HCl)	▪ Elanco	▪ Dogs ▪ Behavioural problems	▪ 15/05/2007 ▪ 16/04/2008 ▪ 210 ▪ 127	▪ 30/05/2008 ▪ 08/07/2008 ▪ 16/07/2008 ▪ OJ C 220/15
▪ Posatex ▪ orbifloxacin, mometasone furoate and posaconazole	▪ Schering Plough Animal Health	▪ Dogs ▪ Treatment of acute and recurrent otitis externa	▪ 17/10/2006 ▪ 15/04/2008 ▪ 210 ▪ 334	▪ 21/04/2008 ▪ 23/06/2008 ▪ 25/06/2008 ▪ OJ C 188/14
▪ Equioxx ▪ firocoxib	▪ Mérial	▪ Horse ▪ Alleviation of pain and inflammation	▪ 19/03/2008 ▪ 14/05/2008 ▪ 55 ▪ 0	▪ 28/03/2008 ▪ 25/06/2008 ▪ 27/06/2008 ▪ OJ C 188/14
▪ Zactran ▪ gamithromycin	▪ Mérial	▪ Cattle ▪ Respiratory disease	▪ 13/03/2007 ▪ 14/05/2008 ▪ 204 ▪ 204	▪ 09/06/2008 ▪ 24/07/2008 ▪ 28/07/2008 ▪ OJ C 220/15

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Trocoxil ▪ mavacoxib	▪ Pfizer	▪ Dogs ▪ Treatment of pain and inflammation associated with degenerative joint disease	▪ 15/05/2007 ▪ 16/07/2008 ▪ 204 ▪ 226	▪ 13/08/2008 ▪ 09/09/2008
▪ Easotic ▪ hydrocortisone aceponate, miconazole nitrate, gentamicin sulphate	▪ Virbac S.A	▪ Dogs ▪ Treatment of otitis externa (QS02CA)	▪ 15/01/2008 ▪ 17/9/2008 ▪ 210 ▪ 36	▪
▪ Duvaxyn WNV ▪ inactivated West Nile Virus	▪ Fort Dodge Animal Health	▪ Horses and ponies ▪ Vaccine to aid in prevention of West Nile Virus (QI05AA)	▪ 14/08/2007 ▪ 17/09/2008 ▪ 210 ▪ 190	▪
▪ Masivet ▪ masitinib	▪ AB Science	▪ Dogs ▪ Mast cell tumours	▪ 13/03/2007 ▪ 18/09/2008 ▪ 182 ▪ 246	▪
▪ Onsior ▪ robenacoxib	▪ Novartis	▪ Cats and dogs ▪ Painkiller	▪ 13/03/2007 ▪ 15/10/2008 ▪ 210 ▪ 371	▪
▪ Acticam ▪ meloxicam	▪ Omnipharm	▪ Dogs ▪ Musculoskeletal	▪ 20/09/2008 ▪ 15/10/2009 ▪ 209 ▪ 210	▪
▪ Loxicom ▪ Meloxicam	▪ Norbrook Laboratories Ltd	▪ Dogs ▪ Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders	▪ 15/01/2008 ▪ 112/11/2008 ▪ 210 ▪ 108	▪
▪ Porcilis PCV	▪ Intervet	▪ Pigs ▪ Immunisation to reduce virus replication of Porcine Circovirus	▪ 14/08/2007 ▪ 12/12/2008 ▪ 209 ▪ 246	▪

Negative Opinions

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal

Withdrawals prior to opinion

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Kexxtone ▪ avilamycin	▪ Elanco	▪ Rabbits ▪ Enteritis due to Cl. perfringens	▪ 15/05/2008 ▪ - ▪ 120 ▪ 362	▪

CVMP Opinions in 2008 on establishment of MRLs for new substances

Positive Opinions

Substance INN	**Therapeutic area** ▪ Target species	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Lectin	▪ Porcine	▪ 18/10/2007 ▪ 16/01/2008 ▪ 90 days ▪ 0 days	▪
▪ Monepantel	▪ Ovine, caprine	▪ 15/12/2008 ▪ 12/11/2008 ▪ 120 ▪ 151	▪

Negative Opinions (Recommendation for inclusion in Annex IV or inability to recommend inclusion in any of the Annexes to Regulation 2377/90)

Substance INN	**Therapeutic area** ▪ Target species	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Isoeugenol	▪ Atlantic salmon	▪ 18/01/2007 ▪ 16/10//2008 ▪ 179 days ▪ 458	▪

Arbitrations and Community Referrals in 2008

Type of referral	**Date of clock start / CVMP opinion**	▪ **Product name** ▪ **INN**
Referral under Art. 35 of Directive 2001/82/EC	16/01/2008 (clock start)	▪ Injectable veterinary medicinal products containing ivermectin indicated for use in cattle ▪ Ivermectin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/01/2007 13/02/2008	▪ Compagel gel for horses ▪ Heparin sodium, levomenthol, hydroxyethyl salicylate
Referral for arbitration – Art.	11/12/2007	▪ Solacyl ▪ Sodium salicylate

Type of referral	Date of clock start / CVMP opinion	▪ **Product name** ▪ **INN**
33(4) of Directive 2001/82/EC	13/02/2008	
Referral under Art. 35 of Directive 2001/82/EC	15/04/2008 (follow up opinion) 19/06/2008	▪ Suramox 15% and Stabox 15% ▪ Amoxicillin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008 (clock start)	▪ ENRO-K 10% oral solution ▪ Enrofloxacin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008 (clock start)	▪ Unisol (avifox) 10% oral solution ▪ Enrofloxacin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008 (clock start)	▪ Pharmasin 100% w/w water soluble granules ▪ Tylosine tartrate
Referral under Art. 35 of Directive 2001/82/EC	11/10/2007 16/07/2008	▪ Baycox 2.5 % ▪ Toltrazuril
Referral under Art. 35 of Directive 2001/82/EC	11/12/2007 16/07/2008	▪ Oral soluble powders containing sodium salicylate, for calves and pigs ▪ Sodium salicylate
Referral for arbitration – Art. 34(1) Directive 2001/82/EC	16/07/2008 (clock start)	▪ Pulmotil 40/100/200 VET Premix ▪ Tilmicosin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/09/2008 (clock start)	▪ Clavobay Lactating Cow ▪ Amoxicillin and clavulanic acid
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/09/2008 (clock start)	▪ Shotaflor 300 mg/ml ▪ Florfenicol
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/09/2008 (clock start)	▪ Fenflor 300 mg/ml ▪ Florfenicol
Referral for arbitration – Art. 34(1) Directive 2001/82/EC	16/09/2008 (clock start)	▪ Pulmotil AC and associated names ▪ Tilmicosin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	15/10/2008 (clock start)	▪ APPM Respipharm ▪ Strains of Actinobacillus pleuropneumoniae
Referral for arbitration – Art. 34(1) Directive 2001/82/EC	15/10/2008 (clock start)	▪ Tiamutin Premix and associated names ▪ Tiamutin Fumarate
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	12/11/2008 (clock start)	▪ Tildren 500 mg ▪ Tiludronic acid (as disodium salt)

Urgent procedures

Type of procedure	CVMP opinion	Product name
Procedure under Art. 78(1) of Directive 2001/82/EC	12/11/2008	▪ Identified veterinary medicinal products containing the alpha2-adrenoreceptor agonists romifidine, xylazine, medetomidine or detomidine

Guidelines and Working Documents in 2008

CVMP Efficacy

Reference number	Document title	Status
EMEA/CVMP/VICH/393388/2006	VICH guideline: GL43 on Target Animal Safety for Pharmaceuticals	Adopted, September 2008

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMEA/CVMP/ERA/418282/2005-Rev.1	Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted, November 2008

CVMP Immunologicals

Reference number	Document title	Status
EMEA/CVMP/IWP/205351/2006	Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus	Adopted, March 2008 (This guideline has been updated following comments received from IFAH Europe)
EMEA/CVMP/IWP/105504/2007-CONSULTATION	Guideline on the requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs)	Adopted for consultation, March 2008 (End of consultation: September 2008)
EMEA/CVMP/IWP/37267/2008	Concept paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue	Adopted, June 2008
EMEA/CVMP/IWP/123243/2006-Rev.1	Guideline on data requirements for IVMPs intended for minor use or minor species/limited markets	Adopted for consultation (following minor revision), July 2008 (End of consultation: October 2008)

EMEA/CVMP/439633/2007	Clarification note on the requirements for starting materials of biological origin	Adopted, September 2008
EMEA/CVMP/VICH/359665/2005	VICH guideline: GL44 on Target Animal Safety for Veterinary Live and Inactivated Vaccines	Adopted, September 2008
EMEA/CVMP/IWP/220193/2008	Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue	Adopted, November 2008

CVMP Pharmacovigilance

Reference number	Document title	Status
EMEA/CVMP/PhVWP/72829/2007	EMEA public bulletin 2007 on veterinary pharmacovigilance	Adopted, February 2008
EMEA/CVMP/VICH/547/00	VICH guideline (GL24) on Management of Adverse Event Reports	Adopted, March 2008
▪ EMEA/CVMP/413/99-Rev.5 ▪ EMEA/CVMP/891/04-Rev.3 ▪ EMEA/CVMP/553/03-Rev.3	Standard lists used for electronic reporting of suspected adverse reactions: ▪ VEDDRA list of clinical terms for adverse reactions in animals ▪ VEDDRA list of clinical terms for adverse reactions in humans ▪ List of species and breeds	Adopted, July 2008
EMEA/123353/2004-Rev.3	Revised Call for Comments on Standard Lists for EudraVigilance Veterinary	Adopted, July 2008
EMEA/CVMP/PhVWP/288284/2007	Use of VeDDRA Terminology for Reporting Suspected Adverse Reactions in Animals	Adopted, July 2008
EMEA/CVMP/PhVWP/4550/2006	Recommendation on management and assessment of Periodic Safety Update Reports (PSURs) of veterinary medicinal products	Adopted, October 2008

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMEA/CHMP/CVMP/QWP/28271 /2008 – CONSULTATION	Reflection paper on the acceptability of water for injections prepared by reverse osmosis	Adopted for consultation, February 2008
EMEA/CVMP/VICH/581467/2007 -CONSULTATION	VICH guideline (GL45) on Quality: Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products	Adopted for consultation, February 2008 (End of consultaion: August 2008)
EMEA/HMPC/CHMP/CVMP/214 869/2006	Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products	Adopted, March 2008

EMEA/CHMP/CVMP/QWP/139037/2008	Question and Answer document on process validation and other quality data requirements	Adopted, June 2008
EMEA/CHMP/CVMP/QWP/136351/2008-CONSULTATION	Concept Paper on the development of a guideline on setting specifications for related impurities in antibiotics	Adopted for consultation, June 2008 (End of consultation: September 2008)
EMEA/CVMP/QWP/846/99-Rev.1	Guideline on Stability Testing: Stability testing of existing active substances and related finished products	Adopted, July 2008
▪ EMEA/CHMP/CVMP/QWP/321287/2008 ▪ EMEA/CHMP/CVMP/QWP/321422/2008 ▪ EMEA/CHMP/CVMP/QWP/321388/2008	Question and Answer documents on: ▪ Glycerol (glycerin) contamination ▪ The harmonised Ph.Eur. General chapter: Uniformity of dosage units (2.9.40) ▪ The calculation of expiry dates	Adopted, July 2008
EMEA/HMPC/CHMP/CVMP/287539/2005-Rev.1	Revised guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products	Adopted for consultation, October 2008 (End of consultation: January 2009)

CVMP Safety

Reference number	Document title	Status
EMEA/CVMP/27466/2008	Report of the Focus group meeting on user safety guideline	Adopted, March 2008
EMEA/CVMP/SWP/173804/2008-CONSULTATION	Concept paper for the revision of the Guideline on User Safety	Adopted for consultation, April 2008. (End of consultation: May 2008)
EMEA/CVMP/520190/2007-CONSULTATION	Reflection paper on injection site residues: Considerations for risk assessment and residue surveillance	Adopted for consultation, June 2008 (End of consultation: September 2008
EMEA/CVMP/SWP/138366/2008	Reflection paper on the new approach developed by JECFA for exposure and MRL assessment of residues of VMP	Endorsed, June 2008, Revision (inserting an introductory note) endorsed, September 2008
EMEA/CVMP/SWP/95682/2007	Reflection paper on assessment of bioavailability of bound residues in food commodities of animal origin	Adopted, September 2008

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/SAGAM/428938/2007	Reflection paper on antimicrobials resistance surveillance as post-marketing authorisation commitment	Adopted, October 2008

EMEA/CVMP/SAGAM/81730/2006-CONSULTATION	Reflection paper on the use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, February 2008. (End of consultation: August 2008)

CVMP General

Reference number	Document title	Status
EMEA/CVMP/28510/2008-CONSULTATION	Guideline on Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats	Adopted for consultation, January 2008. (End of consultation: July 2008)
EMEA/328/98-Rev.3	Guidline on the acceptability of names for veterinary medicinal products processed through the centralised procedure	Adopted, January 2008
EMEA/410/01-Rev.4	Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Adopted, February 2008
EMEA/CVMP/182112/2006	CVMP Reflection Paper regarding the assessment of environmental risks of veterinary medicinal products	Adopted for consultation, March 2008 (End of consultation: June 2008)
EMEA/CVMP/430630/2006 – Rev.1	Reflection paper on Criteria for requiring one additional five-year renewal on pharmacovigilance grounds	Adopted, May 2008 (to become part of Volume 9B, which will be published for consultation shortly)
EMEA/CVMP/PhVWP/430286/2007	Volume 9B of the Rules Governing Medicinal Products in the European Union - Pharmacovigilance for Veterinary Medicinal products	Adopted, September 2008 (for submission to the European Commission)
EMEA/CVMP/248499/2007	Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted for second consultation, October 2008 (End of consultation: January 2009)